REMARKS

Applicant respectfully submits this amendment to clarify the claim language consistent with the fundamental mechanism of the inventive dissolution and to note the resulting performance improvements relative to the prior art. Claims 1-14 stand rejected under 35 USC 112, second paragraph, as being indefinite with respect to the ratio encompassed by the claims. Claims 1, 2, 5, 6 and 8-14 stand rejected under 35 USC 102(b) as anticipated by Amidon et al. (U.S. Patent 5,834,022). Lastly, claims 3, 4 and 7 stand rejected over Amidon et al. in view of Woo (U.S. Patent 5,589,455) and Gennaro et al. (Remington's Pharm. Sci. 18th Ed. 1990, pp. 1662-4).

Support for the claim amendments is found inter alia in the specification at page 1, line 14; page 3, line 21 – page 4, line 3; and page 16, lines 2-17. As such, it is submitted that no new matter has been added by way of this amendment.

Remarks Directed to Rejection under 35 USC 112, Second Paragraph

Independent claims 1 and 12 have been amended to clarify the determination of the ratio of initial mass of the particle to boundary layer volume at the solid-liquid interface as used to increase the dissolution rate of a poorly soluble drug. It is also noted that C_{SAT}, a concentration variable corresponding to the claimed ratio, is a variable that one attempts to maximize rather than a constant value. Applicant submits that independent claims 1 and 12 are explicit in defining how one increases drug concentration by incorporating definitional elements from Equation 1 found at page 1, line 14. It is believed that through incorporation of the expression of Formula 1 (found in the specification at page 1, line 14), it would become clear to one skilled in the art that the initial mass of the particle is controlled by drug particle size, while the volume of the boundary layer is reduced to encompass the entire initial mass of the particle through the choice of surfactant or emulsion/microemulsion.

In light of the above amendments and remarks, it is now believed that the rejection of claims 1-14 under 35 USC 112, second paragraph, is no longer proper and it is respectfully requested that it be withdrawn.

Remarks Directed to Rejection of Claims 1, 2, 5, 6 and 8-14 under 35 USC 102(b) as Anticipated by Amidon et al.

Amidon et al. is cited as teaching a coating composition consisting essentially of gelatin and lecithin, having a drug disposed within the boundary layer that increases dissolution of cyclosporin and griseofulvin by 20% and 40% respectively in the drug delivery system disclosed therein.

Independent claims 1 and 12 have been amended to clarify that the decrease in the amount of solubilizing agent needed to dissolve a drug particle is decreased relative by controlling the volume of the boundary layer relative to the drug particle mass (see specification page 2, line 21 – page 3, line 4). The presence of micelles within the solubilizing agent reduces the boundary layer volume and thereby serves to increase drug dissolution. In contrast to the pending claims, Amidon et al. is silent as to the presence and/or efficacy of micelles. Amidon et al. is likewise silent as to the claim limitations with respect to using such micelles to control boundary layer volume. Since each of the pending claims recites a limitation not found in Amidon et al. with respect to the ratio of drug particle mass to boundary layer volume and further represent an improvement in performance thereover, it is believed that the pending claims are not anticipated by Amidon et al.

In light of the above amendments and remarks, it is now believed that pending claims 1, 2, 5, 6 and 8-14 are not anticipated by Amidon et al. under 35 USC 102(b). Withdrawal of the rejection is respectfully requested.

Remarks Directed to Rejection of Claims 3, 4 and 7 under 35 USC 103(a)

In view of Applicant's belief as to the allowability of independent claim 1, dependent claims 3, 4 and 7 are likewise submitted to be allowable. Withdrawal of the rejection under 35 USC 103(a) is requested.

Summary

Claims 1-14 are pending in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is solicited. If the Examiner finds to the contrary, it is respectfully requested that the undersigned in charge of this application be called at the telephone number given below in order to resolve any remaining issues.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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I hereby certify that this paper or fee (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, Washington, D.C. 20231.

Janice R. Kuehn

JANICE R KUEHN

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

A substitute specification is provided to correct equation numbering errors. It is submitted that no new matter has been added by way of this substitution. A marked-up copy is also provided to identify changes made by way of the substitution.

IN THE CLAIMS:

Claim 1 has been amended as follows:

1. (Twice Amended) A pharmaceutical delivery vehicle, said delivery vehicle comprising:

a drug particle having an initial mass disposed within a diffusional boundary layer comprising a matrix and a solubilizing agent, the diffusional boundary layer having a volume;

said matrix and said solubilizing agent forming the diffusional boundary layer,

the ratio of the initial mass of the drug particle M_P to the volume of the diffusional boundary layer V_{BL} defines a concentration of a drug of the drug particle at a solid-liquid interface as

$$\frac{\delta}{SA \circ D}\,\frac{dm}{dt}$$

where δ is the thickness of the diffusional boundary layer, SA is the surface area of said drug particle available for dissolution, D is the diffusion coefficient of the drug in solid form, m is the mass of the drug particle in solid form, and t is time wherein said drug disposed in the drug particle has a solubility greater than twofold that of said drug in a bulk form by maintaining a region adjacent to said drug particle that

contains solubilizing agent micelles to solubilize same through control of the volume of the diffusional boundary layer [being such that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter].

Claim 12 has been amended as follows:

12. (Twice Amended) A pharmaceutical delivery vehicle, said delivery vehicle comprising:

a drug particle having an initial mass disposed within a diffusional boundary layer having a volume, the ratio of the initial mass of the drug particle M_P to the volume of the diffusional boundary layer V_{BL} defines a concentration of a drug of the drug particle at a solid-liquid interface as

$$\frac{\delta}{SA \circ D} \frac{dm}{dt}$$

where δ is the thickness of the diffusional boundary layer, SA is the surface area of said drug particle available for dissolution, D is the diffusion coefficient of the drug in solid form, m is the mass of said drug particle in solid form, and t is time wherein said drug disposed in the drug particle has a solubility greater than that of said drug in a bulk form by maintaining a region adjacent to said drug particle that contains solubilizing agent micelles to solubilize same through control of the volume of the diffusional boundary layer [being such that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter].

Claims 15-20 have been canceled with prejudice as being directed to non-elected subject matter.